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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,285	08/10/2001	Jian-Qiang Fan	2420/1J672US2	6863

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,285	FAN ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4,& 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-9 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 rejected under the judicially created doctrine of double patenting over claims 1-7 of U. S. Patent No. 6,274,597 B1 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: In claim 1, applicant claims "A method of enhancing the activity of lysosomal α-galactosidase A in mammalian cells comprising administering an effective amount of a

compound selected from the group consisting of 2,5-dideoxy-2,5-imino-D-mannitol, 3,4-diepi-α-homonojirimycin, 5-O-α-D-galactopyranosyl-α-homonojirimycin, 1-deoxygalactonojirimycin, 4-epi-fagomine, calystegine A_3, calystegine B_2, and calystegine B_3, and N-alkyl derivatives thereof" In claim 2, applicant claims "the method of claim 1 wherein the lysosomal α-galactosidase A is a mutant form which is present in patients with Fabry disease." In claim 3, applicant claims "The method of claim 1 wherein said cells are human cells." In claim 4, applicant claims "the method of claim 3 wherein said cells are the cells of a patient with Fabry disease."

Fan et al., in claim 1, claim "A method of increasing the activity of a mutant form of lysosomal α-galactosidase A in mammalian cells comprising administering an effective amount of a compound selected from the group consisting of 2,5-dideoxy-2,5-imino-D-mannitol, 3,4-diepi-α-homonojirimycin, 5-O-α-D-galactopyranosyl-α-homonojirimycin, 1-deoxygalactonojirimycin, and 4-epi-fagomine." In claim 2, Fan et al. claim "the method of claim 1 wherein the lysosomal α-galactosidase A is a mutant form which is present in patients with Fabry disease." In claim 3, Fan et al. claim "The method of claim 1 wherein said cells are human cells." In claim 4, Fan et al. claim "the method of claim 3 wherein said cells are the cells of a patient with Fabry disease."

The difference between applicant's claimed method and the method of Fan et al. is that applicant's group of compounds used to enhance or increase the enzyme activity consists of the additional compounds, calystegine A_3, calystegine B_2, and calystegine B_3, and N-alkyl derivatives thereof. However, all other the compounds used by Fan et al. to enhance or increase the activity of lysosomal α-galactosidase A are also claimed by the applicant.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method and compounds of Fan et al., and to group Fan et al. compounds with other compounds which have the use and same effect.

One having ordinary skill in the art would have been motivated, to use the method and compounds of Fan et al., and to group Fan et al. compounds with other compounds which have the same use and effect. It should be noted that claims 1 and 8 which are drawn to a method of enhancing the activity of lysosomal α-galactosidase A (non-mutant form) in mammalian cells comprising administering an effective amount of the compounds are also encompassed by the aforementioned rejection, since it is obvious to treat the lysosomal α-galactosidase A (non-mutant form) with same said compounds as those used by Fan et al. to treat the mutant form of lysosomal α-galactosidase A.

In claim 5, applicant claims "A method of treating Fabry disease comprising administering an effective amount of a compound selected from the group consisting of 2,5-dideoxy-2,5-imino-D-mannitol, 3,4-diepi-α-homonojirimycin, 5-O-α-D-galactopyranosyl-α-homonojirimycin, 1-deoxygalactonojirimycin, 4-epi-fagomine, calystegine A_3, calystegine B_2, and calystegine B_3, and N-alkyl derivatives thereof." In claim 6, applicant claim "The method of claim 5 wherein said compound is 1-deoxygalactonojirimycin or 3,4-diepi-α-homonojirimycin. In claim 7, applicant claim "The method of claim 6 wherein said compound is 1-deoxygalactonojirimycin."

Fan et al., in claim 5, claims "A method of treating Fabry disease comprising administering an effective amount of a compound selected from the group consisting of 2,5-dideoxy-2,5-imino-D-mannitol, 3,4-diepi-α-homonojirimycin, 5-O-α-D-galactopyranosyl-α-homonojirimycin, 1-deoxygalactonojirimycin, and 4-epi-fagomine." In claim 6, Fan et al. claim

"The method of claim 5 wherein said compound is 1-deoxygalactonojirimycin." In claim 7, Fan et al. claim "The method of claim 5 wherein said compound is 1-deoxygalactonojirimycin or 3,4-diepi-α-homonojirimycin."

The difference between applicant's claimed method and the method of Fan et al. is that applicant's group of compounds used to treat Fabry disease consists of the additional compounds, calystegine A_3, calystegine B_2, and calystegine B_3, and N-alkyl derivatives thereof. However, all other the compounds used by Fan et al. to treat Fabry disease are also claimed by the applicant.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method and compounds of Fan et al., and to group Fan et al. compounds with other compounds which have the same use and effect.

One having ordinary skill in the art would have been motivated, to use the method and compounds of Fan et al., and to group Fan et al. compounds with other compounds which have the same use and effect. Claim 9, which is drawn to a method of treating Fabry disease comprising administering an effective amount of a compound of a given formula, is also encompassed by this rejection, since the compound, 1-deoxygalactonojirimycin which is used by Fan et al. to treat Fabry disease is also represented by the given formula.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

May 28, 2003.

SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600